

**Remarks**

This Amendment is in response to the Office Action dated **February 3, 2010**.

Claims 1-41 are pending in this Application. Claims 31-33 have been withdrawn from consideration. Claims 1-30 and 34-41 are rejected. Claims 1-30 and 34-41 are rejected under 35 U.S.C. § 112(2<sup>nd</sup> paragraph). Claims 1, 3, 5, 7, 9 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Buirge US 5,735,897 as evidenced by Beall US 4,729,892. Claims 34 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Buirge as evidenced by Beall. Claims 1-29 and 34-41 are rejected under 35 U.S.C. § 103(a) as being obvious over Michal US 6,287,285 in view of Ronan US 6,060,534, Brazel, C.S. et al. (Proceedings of the Second Joint EMBS/BM Conference) and Weissleder US 5,514,379. Claim 30 is rejected under 35 U.S.C. § 103(a) over Michal in view of Ronan, Brazel and Weissleder and further in view of Wang US 6,135,992.

Claims 1, 2, 19 and 34 have been amended to clarify the claims. Support for these amendments can be found at least in paragraphs [0011] and [0014]. No new matter has been added.

The rejection under 35 U.S.C. § 112(2<sup>nd</sup> paragraph) are overcome.

The rejections under 35 U.S.C. § 102(b) are traversed.

The rejections under 35 U.S.C. § 103(a) are traversed.

Applicant notes that the Office Action asserts that the pending claims have not been afforded the benefit of the filing date of the '907 Application and that the effective filing date of this Application is January 9 2004. Applicant reserves the right to contest this issue at a later date.

In light of the following comments, reconsideration is requested.

***Claim Rejections –35 U.S.C. § 112(2<sup>nd</sup> paragraph) –***

Claims 1-30 and 34-41 are rejected under 35 U.S.C. § 112(2<sup>nd</sup> paragraph) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This rejection is overcome. Applicants have amended claims 1 and 34 removing the phrase “differentiated from the environment.” Applicants have also amended the phrase “the same or different” to read “different”. In claim 19, the term “first” has been

changed to “inner.” Claim 37 has been similarly amended. The Applicants submit that the pending claims are now in allowable condition. The Applicants respectfully request withdrawal of the rejection.

***Claim Rejections –35 U.S.C. § 102(b) --***

**Claims 1, 3, 5, 7, 9 and 19**

Claims 1, 3, 5, 7, 9 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Buirge US 5,735,897 as evidenced by Beall US 4,729,892. This rejection is traversed. Buirge as evidenced by Beall does not teach each and every element of the Applicant’s claims.

Claim 1 recites:

[A] hydrogel coating disposed over at least a portion of the substrate surface and comprising inner and outer regions, said inner region exhibiting more absorption upon hydration than does said outer region, said inner region comprising a first hydrogel polymer and said outer region comprising a second hydrogel polymer, said first and second hydrogel polymers being different, and said hydrogel coating further comprising a contrast agent visible under magnetic resonance imaging.

As recited, claim 1 requires “said hydrogel coating further comprising a contrast agent.” Claim 1 therefore requires a contrast agent in addition to the hydrogel. This feature is absent from Buirge.

Buirge teaches a stent having hydrogel layers. However, Buirge does not teach the addition of a separate contrast agent to the hydrogel as required by claim 1. Therefore, Buirge does not anticipate claim 1.

Moreover, neither does Beall teach “said hydrogel coating further comprising a contrast agent.” Beall teaches the use of hydrogel slurries acting as a contrast agent when viewed under Magnetic Resonance Imaging (MRI). Beall does not teach the addition of a separate contrast agent to the hydrogel as required by claim 1. Therefore, Buirge as evidenced by Beal does not anticipate Applicants’ claim 1.

Claims 3, 5, 7, 9 and 19 depend either directly or indirectly from claim 1. These claims are therefore patentable for at least the reasons cited above. The Applicants respectfully request withdrawal of the rejection.

Claims 34 and 37

Claims 34 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Buirge as evidenced by Beal.

The header for the rejection mentions Buirge and Beal. The discussion that follows mentions Ronan. Applicant requests clarification as to whether the rejection is based on Buirge or Ronan.

Also, Claim 34 has been amended to clarify that the hydrogel further comprises a magnetic resonance imaging contrast agent. Thus, the contrast agent is in addition to the hydrogel itself. As discussed above with respect to claim 1, this is not disclosed in Buirge as evidenced by Beal.

Withdrawal of the rejection is respectfully requested.

*Claim rejections –35 USC §103(a) –*

Claims 1-29 and 34-41 are rejected under 35 U.S.C. § 103(a) as being obvious over Michal in view of Ronan, Brazel and Weissleder. This rejection is traversed.

The Applicants note the Office Action fails to mention with specificity a number of the claims which are being addressed in the rejection. For example, claim 34 is not directly mentioned. The Applicants request that any future Office Action include the specific claim number and an articulated reason for its treatment.

The Office Action maintains that Michal teaches medical devices having an outer hydrophilic coating, where the coating can comprise an inorganic ion. The Office Action acknowledges, however, that:

Michal does not teach that the device further contains an ionic crosslinking agent or a contrast agent (other than the hydrogel composition itself) contained in the coating.

Michal also does not teach why the outer layer of the device would contain a higher crosslink density than the inner region.

The Office Action relies on Ronan for the use of an ionic crosslinking agent and asserts:

such as medicines. (See column 6, lines 37-40.) The application of the ionic crosslinking agent to the device taught by Michal on the surface of the device through dipping or spraying the device would have been obvious to the skilled artisan at the time of the invention given the teachings of Ronan, and would have been an obvious choice given the ease of the procedure. The depth of the crosslinking would depend upon the

and further:

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to form a catheter coated by a layer of alginate and a non-ionic crosslinking as taught by Michal with the further addition of an ionic crosslinking agent and medicines as taught by Ronan. The skilled artisan would have been motivated to use the methods taught by Ronan for improving catheters coated with alginate by using both ionic and non-ionic crosslinking agents and medicines in order to form a medicated catheter with greater stiffness, modulus, yield stress, and strength, the ability to adjust its shape after implantation, and having the ability to deliver therapeutic drugs to a patient.

Applicant disagrees. Ronan discloses making a device such as a stent or catheter by shaping a crosslinked hydrogel (see, for example, the abstract). Thus, the very structure of the Ronan device is formed by the hydrogel, Michal, on the other hand, is directed to a coating on a pre-existing device. Physical properties of the Michal device such as stiffness and strength and the ability to adjust its shape would be expected to be controlled by the nature of the underlying material of the device and not, primarily, by Ronan-like adjustments to the coating. Thus, the proposed motivation is lacking.

Even if, for the sake of argument only, the combination were made, the resulting device would not have the recited inner and outer regions.

To that end, the Office Action further admits that the combination of Michal and Ronan does not teach a reason for the outer layer of the device to contain a higher crosslink density or the addition of a contrast agent. The Office Action states, however, that:

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to modify the medicated hydrogel coated device of Michal and Ronan with a higher crosslinking density at the surface of device (as taught by Brazel) in order to form an improved drug releasing catheter without any burst effects for the drugs contained within the hydrogel coated catheter. The skill artisan would have been

Applicant disagrees. Brazel's teaching of a higher crosslinking density at the surface (via covalent crosslinking – Brazel uses glutaraldehyde) of the device is at odds with the teachings of Ronan. Ronan teaches that it is desirable to do selective in-vivo stripping of crosslinking ions to produce a softer, more flexible implant. Providing a higher (covalent) crosslink density at the surface of the device would be expected to result in a device of diminished softness, defeating one of the stated purposes of the Ronan teaching.

Moreover, in light of Brazel's teaching concerning the covalent surface crosslinking diminishing the "burst", one of ordinary skill in the art would not make the proposed combination because covalently crosslinking the outer surface of the Ronan device would be expected to hinder the stripping of the ionic crosslinking agents as taught by Ronan.

As such, the combination is not seen to be appropriate.

Weissleder does not remedy the above deficiency.

Therefore, claims 1-29 and 34-41 are not obvious in light of these prior art references. The Applicants respectfully request withdrawal of the rejection.

Applicant further notes that claim 34 and its dependent claims have been amended to recite that the outer region is differently crosslinked from the inner region, the outer region being ionically crosslinked and the inner region being covalently crosslinked.

The Office Action has not established how the combination of the above-mentioned references would render these features obvious.

#### Claim 30

Claim 30 is rejected under 35 U.S.C. 103(a) as being obvious over Michal in view of Ronan, Brazel and Weissleder in further view of Wang US 6,135,992. This rejection is traversed.

Claim 30 depends indirectly from claim 1. Wang does nothing to cure the deficiencies of Michal, Ronan, Brazel and Weissleder regarding claim 1. "Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Claim 30 is therefore patentable for at least the reasons cited previously regarding claim 1. The Applicants respectfully request withdrawal of the rejection.

### ***Conclusion***

In view of the preceding arguments, Applicants submit that the Application is in condition for allowance. Favorable consideration and early action to that effect are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this Application in better condition for allowance the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: March 29, 2010

By: /Jonathan Grad/  
Jonathan Grad  
Registration No.: 41795

6640 Shady Oak Rd., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001